510(k) Summary*

Sepax Cell Separation System and single use kits

510k owner: Biosafe SA
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Product:
- Trade name: Sepax Cell Separation System and single use kits
- Common name: Sepax 2 system
- Classification name: Cord blood processing system and storage container
- Classification: class II (Special controls, 21 CFR 864.9900)
- Product code: OAO

Predicate device:
Sepax Cell Separation System and single use kits cleared as bk110022

Device Description:
The Sepax system consists of:
- The Sepax Main Unit (S-100): provides centrifugal and axial displacement drive to the chamber on the single-use separation kit, as well as drive to the directional valves. The main unit can be equipped with application specific Sepax software protocols.
- The Single-use kit (CS-xxx.x): contains the cord blood in a sterile environment during the complete operation – valves control the flow of cord blood to the correct bag.

The list of single use kit compatible with Sepax system is extended to the families: CS-430.x, CS-530.x, CS-540.x and CS-570.x.

Intended Use:
The Sepax system is a cord blood cell processing system intended for laboratory use in exclusive combination with a compatible single-use separation kit supplied by Biosafe. The cord blood to be processed has been previously collected and transported to the laboratory by other means.
The Sepax system allows the fast, automated and reproducible separation of cord blood. The Sepax system is not intended for use in transfusion applications at bedside, where blood circulates directly between a patient and the Sepax unit.

*As described in 21 CFR 807.92

Technological Characteristics:
The Notification of modification under the present 510(k) concerns only the separation chamber from the Single-Use kit in which the following changes are applied:

- The syringe piston is manufactured as a single unique part
- The syringe piston material

	Current Sepax 2	**Sepax 2 including modification of the piston**
Clearance	Cleared under 510(k) bk110022.	Notification of modification under the present special 510(k)
General		
Intended use / Indication for use	The Sepax system is a cord blood cell processing system intended for laboratory use in exclusive combination with a compatible single-use separation kit supplied by Biosafe. The cord blood to be processed has been previously collected and transported to the laboratory by other means. The Sepax system allows the fast, automated and reproducible separation of cord blood. The Sepax system is not intended for use in transfusion applications at bedside, where blood circulates directly between a patient and the Sepax unit.	Same
Fundamental scientific technology	The machine in conjunction with a sterile single use kit is used for cord blood cell separation. Rotational drive is provided by the electric motor, while piston displacement is assured by compressed air fed through a sterile filter of the chamber.	Same
Labelling	Operator manual describes the procedures steps and the machine use.	Same

Safety and Performance:
Design control activities have been performed to ensure that the safety and performance are substantially equivalent to the predicate device.

Conclusion:
It is the conclusion of Biosafe, that the changes in the piston of the Sepax 2 system are substantially equivalent to the cleared device under 510(k): BK110022.

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